SECTION 7 - SUMMARY OF SAFETY AND EFFECTIVENESS

K102130

(Premarket Notification [510(k)] Number)

AUG 26 2010

1. Submitter Information

Manufacturer Name & Address
Mazor Surgical Technologies Ltd.
7 HaEshel Str.
P.O.B. 3104
Southern Caesarea Industrial Park, 38900
ISRAEL

Official Correspondent
Ahava Stein
A. Stein – Regulatory Affairs Consulting
20 Hata'as St.
Kfar Saba 44425
Israel

2. Date Prepare: July 2010

3. Device Name

Proprietary Name:	TenZing System
Common / Usual Name:	Combination of: 1. Spinal Stereotaxic instrument; and 2. 3-D Reconstruction Tool for Mobile X-Ray Devices
FDA Classification Name:	1. 21 CFR 882.4560; Stereotaxic instrument with product code HAW. 2. 21 CFR 892.2050; System, image Processing, Radiological and product code LLZ.
FDA Classification:	Class II, Product Code HAW and LLZ

4. Predicate Devices

The TenZing System is substantially equivalent to the following devices

Manufacturer	Device	510(k)	Date Cleared
Mazor Surgical Technologies	SpineAssist	K073467	05/23/2008
Mazor Surgical Technologies	C-InSight	K081672	08/15/2008

5. Device Description

The TenZing system is a device modification of the SpineAssist system, designed to incorporate both the original SpineAssist system and the C-InSight system in one workstation. The TenZing console is identical to the SpineAssist console. The system is intended to be used in a variety of hospital locations (e.g., OR, trauma unit, etc.).

The main components of the TenZing System include:

A. Workstation

B. SpineAssist accessories:
   - Surgical Accessories Kit
   - Setup Kit

C. SpineAssist Device

D. C-InSight accessories:
   - Spine Target Kit
   - Extremities Target Kit

E. Image Adaptor

F. Spine Assist Disposable kits

G. C-InSight Sterile Sheath Disposable kits

6. Intended Use / Indications

The TenZing System is a combination of the SpineAssist System and C-InSight System, allowing the C-InSight application to run on the SpineAssist Workstation:

The SpineAssist™ System is indicated for precise positioning of surgical instruments or implants during general spinal surgery. The SpineAssist™ System may be used in either open or percutaneous procedures.

The C-InSight software provides a processing and conversion of 2D fluoroscopic projections from standard C-Arms into volumetric 3D image. It is intended to be used whenever the clinician and/or patient benefits from generated 3D imaging of high contrast objects particularly in orthopedic applications.

7. Performance Standards

There are no performance standards under the Federal Food, Drug and Cosmetic Act, for the TenZing device.

8. Performance Testing

The TenZing System software was subject to software validation testing in accordance with the FDA Guidance for the Premarket Submissions for Software Contained in Medical Devices (January 11, 2002).

9. Technological Characteristics Compared to Predicate Device

The technological characteristics, e.g., overall design, materials, mechanism of action, mode of operation, performance characteristics, etc., and the intended use of the TenZing device are substantially equivalent to the predicate device cited above.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mazor Surgical Technologies, Ltd.
% Ms. Ahava Stein
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Kafr Saba, 44425
ISRAEL

AUG 2 6 2010

Re: K102130
Trade/Device Name: TenZing System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW and LLZ
Dated: July 27, 2010
Received: July 29, 2010

Dear Ms. Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

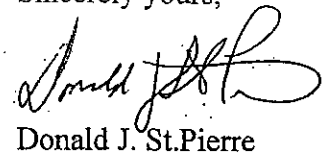
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K102130

Indications for Use

510(k) Number (if known): K102130

Device Name: TenZing System

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102130